

**ADDRESSES)** electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on [www.regulations.gov](http://www.regulations.gov) may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010-22496 Filed 9-8-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-E-0416]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; IXIARO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for IXIARO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public

Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product IXIARO (Japanese Encephalitis Virus, Vaccine Inactivated, Adsorbed). IXIARO is indicated for active immunization for the prevention of disease caused by Japanese encephalitis virus in persons 17 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IXIARO (U.S. Patent No. 6,309,650) from Chiel Jedang Corp. and Walter Reed Army Institute of Research, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of IXIARO represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for IXIARO is 3,461 days. Of this time,

2,994 days occurred during the testing phase of the regulatory review period, while 467 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* October 10, 1999. The applicant claims October 9, 1999, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was October 10, 1999, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 20, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for IXIARO (BLA B125280/0) was initially submitted on December 20, 2007.

3. *The date the application was approved:* March 30, 2009. FDA has verified the applicant's claim that BLA B125280/0 was approved on March 30, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,588 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by November 8, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 8, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with

the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on [regulations.gov](http://regulations.gov) may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

Jane A. Axelrad,  
Associate Director for Policy, Center for Drug  
Evaluation and Research.

[FR Doc. 2010-22394 Filed 9-8-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[ATSDR-265]

#### Development of Set 24 Toxicological Profiles

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (DHHS).

**ACTION:** Notice.

**DATES:** Profiles will be available to the public on or about October 17, 2010.

**SUMMARY:** The Agency for Toxic Substances and Disease Registry (ATSDR) of the Department of Health and Human Services is developing Set 24 Toxicological Profiles. Set 24 Toxicological Profiles consists of one new draft and one updated draft. Electronic access to these documents will be available at the ATSDR Web site: <http://www.atsdr.cdc.gov/toxpro2.html>.

#### Set 24 Toxicological Profiles

The following toxicological profiles are now being developed:

Toxicological profile	CAS number
Toxaphene .....	8001-35-2
Trichlorobenzene*	
1,2,3-Trichlorobenzene	87-61-6
1,2,4-Trichlorobenzene	120-82-1
1,3,5-Trichlorobenzene	108-70-3
Trichlorobenzene ....	12002-48-1

\* Denotes new profile.

**SUPPLEMENTARY INFORMATION:** The Superfund Amendments and Reauthorization Act of 1986 (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA)

with regard to hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List. Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances (<http://www.atsdr.cdc.gov/cercla/07list.html>). This list names 275 hazardous substances that pose the most significant potential threat to human health as determined by ATSDR and EPA. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on March 6, 2008 (73 FR 12178). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); November 7, 2003 (68 FR 63098); and December 7, 2005 (70 FR 70284).

Notice of the availability of drafts of one updated and one new toxicological profile for public review and comment will be published in the **Federal Register** on or about October 17, 2010, with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments will be addressed, and where appropriate, revisions will be incorporated into each profile.

#### FOR FURTHER INFORMATION CONTACT:

Commander Jessilyn B. Taylor,  
Division of Toxicology and  
Environmental Medicine, Agency for  
Toxic Substances and Disease Registry,  
1600 Clifton Road, NE., Mail Stop F-62,  
Atlanta, GA 30333; telephone (770)  
488-3313; e-mail: [JBTaylor@cdc.gov](mailto:JBTaylor@cdc.gov).

Dated: September 3, 2010.

Ken Rose,

Associate Director, Office of Policy, Planning  
and Evaluation, National Center for  
Environmental Health/Agency for Toxic  
Substances and Disease Registry.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0451]

#### Draft Guidance for Industry on Suicidality: Prospective Assessment of Occurrence in Clinical Trials; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Suicidality: Prospective Assessment of Occurrence in Clinical Trials." The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidality in clinical trials of drug and biological products. Specifically, this guidance addresses FDA's current thinking regarding the importance of suicidality assessment in psychiatric and nonpsychiatric drug trials and the general principles for how best to accomplish this assessment during drug development.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 8, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Thomas Laughren, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4114, Silver Spring, MD 20993-0002, 301-796-2260.